

Ms. Sheryl Reilly
Biopesticides and Pollution Prevention Division (751,1C)
Office of Pesticide Programs
U.S. Environmental Protection Agency
One Potomac Yard,
2777 S. Crystal Dr.,
Alexandria, VA 22202

Attn: Denise Greenway

December 22, 2008

Subject: Registration application for BCS Cry1Ab cotton event T304-40 cotton. Active ingredient Bacillus thuringiensis Cry1Ab protein and the genetic material necessary for its production (pTDL008)

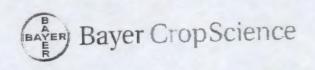
EPA CODE B800

Dear Ms. Greenway:

Bayer CropScience (BCS) respectfully submits this registration application for the active ingredient *Bacillus thuringiensis* Cry1Ab protein and the genetic material necessary for its production in event T304-40 cotton plants under section 3 of the Federal Insecticide, Fungicide and Rodenticide Act. The *Bacillus thuringiensis* Cry1Ab protein and the genetic material necessary for its production in event T304-40 cotton plants is covered by the existing tolerance exemption issued under 40 CFR 180.1173 for the *Bacillus thuringiensis* Cry1Ab delta-endotoxin and the genetic material necessary for its production in all plants.

With this letter and enclosed materials, BCS is applying for a registration of Cry1Ab cotton event T304-40. BCS does not intend to offer this individual product for sale. BCS intends to produce commercially a cotton line called TwinLink<sup>TM</sup> cotton, obtained by conventional breeding of the Cry1Ab cotton event T304-40 and the Cry2Ae cotton event GHB119. A registration application for the Cry2Ae cotton and the combined event are being submitted concurrently in a separate application.

Bayer CropScience (BCS) has developed cotton [Gossypium hirsutum] plants that express an insecticidal protein, Cry1Ab, from a common soil bacterium, Bacillus thuringiensis subsp. berliner (B.t. berliner). The Cry1Ab protein is effective in controlling lepidopteran larvae such as bollworm (CBW, Helicoverpa zea) and tobacco budworm (TBW, Heliothis virenscens) larvae, which are a common pest of cotton. These pests cause severe economic damage to the cotton crop if not controlled. If controlled by chemical pesticides, there is the need for large input annually to control these pests. These plants also contain herbicide tolerant inert ingredient as a selectable marker, the phosphinothricin acetyltransferase (PAT) protein that confers tolerance to glufosinate-ammonium herbicides. Small scale field trial experiments of cotton expressing Cry1Ab protein have shown the plant's ability to protect itself against these pests. This cotton line has been field tested in small scale filed trial experiments, conducted under notifications granted by the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS). An Experimental Use Permit 264-EUP-140 has been granted for this product in 2006 and 2008.



Transgenic cotton plants expressing Cry1Ab protein provide an excellent addition to growers' options for insect control that reduces or eliminates the need for other insecticide inputs and fits well within an integrated pest management program. Cry1Ab is a protein familiar to the Agency but is has not been used in commercial cotton as a Plant Incorporated Protectant (PIP).

The cry1ab gene was isolated from a B.t. berliner strain 1715 and modified for expression in plants. The sequence of the protein is compared with the sequence of Cry1Ab proteins used in commercial bio-pesticides such as Dipel® and in transgenic commercial events such as Bt¹1, which have been approved world-wide by various agencies. Since the trypsin-resistant core from all Cry1Ab proteins have identical N-termini and a similar sequence, it is concluded that BCS' Cry1Ab protein will be as safe as the Cry1Ab proteins already used commercially.

This application contains three copies of the following required information, as defined in EPA form 8570-1, and five copies of draft labeling.

Volume I

Cover letter (this letter)
Transmittal document
Application for Pesticide Registration (EPA Form 8570-1)
Certification with Respect to Citation of Data (EPA Form 8570-34)
Confidential Statement of Formula (EPA Form 8570-4)
Proposed label
Confidentiality classification
Data matrix
Data matrix blacked out

Volume II

Product Characterization of Cry1Ab cotton event T304-40

Volume III

Product Characterization - Nutritional Characterization.

Volume IV

Protein Expression Analysis

Volume V

Analyses of Raw Agricultural Commodity

Volume VI

Structural and Functional Equivalence of Cry1Ab and PAT/bar Proteins Produced in bacteria and plant

Volume VII

ORF Analysis - Toxicology (human health assessment)

Volume VIII

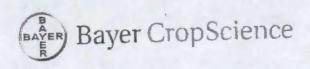
Cry1Ab protein: In vitro digestibility study in simulated intestinal fluid.

Volume IX

Cry1Ab protein: In vitro digestibility study in human simulated gastric fluid.

Volume X

Cry1Ab protein: Epitope homology, N-glycosylation and overall amino acid sequence homology search with known toxins and allergens.- supplemental.



Volume XI

Cry1Ab protein: Acute toxicity by oral gavage in mice.

Volume XII

Cry1Ab Protein: Heat Stability study.

Volume XIII

Toxicology (Human Health Assessment): History of Safe Use History of Safe Use.

Volume XIV

Summary of Non-Target Organism Testing.

Volume XV

Honey Bee

Volume XVI

Ladybug

Volume XVII

Green Lacewing

Volume XVIII

Collembola

Volume XIX

Waiver for Non-target Soil Invertebrate Study: Earthworm.

Volume XX

Water Fleas -Daphnia magna

Volume XXI

Bioassay to Determine the DT50 of the Cry1Ab Protein Produced from Escherichia coli after Aerobic Soil Degradation.

Volume XXII

Efficacy Assessment (Field and Laboratory)

Volume XXIII

Waiver from the Requirement to Prepare a Public Interest Document.

Volume XXIV

Waiver from the Requirement to Develop an Insect Resistance Management Plan.

Volume XXV

Detection Methods - rt PCR.

Volume XXVI

Detection Methods - LFS.

Volume XXVII

Detection Methods - ELISA.



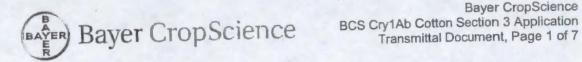
BCS respectfully requests that BPPD evaluate this application in time to grant a registration January 1, 2010. We request that this submission is processed concurrently to the Cry2Ae cotton submission as the commercial product is dependent on both registrations.

Please do not hesitate to contact me at (919) 549 2159, or FAX: (919) 549 3929 or Email: ali.scott@bayercropscience.com

Sincerely,

Ali Scott Ph.D.

Manager, Regulatory Affairs Region Americas



### TRANSMITTAL DOCUMENT

#### SUBMITTED BY

Bayer CropScience LP- BioScience P.O. Box 12014 2 T.W. Alexander Dr. Research Triangle Park, NC 27709

## REGULATORY ACTION IN SUPPORT OF WHICH THIS PACKAGE IS SUBMITTED

Section 3 Registration Request for Bacillus thuringiensis subsp. berliner Cry1Ab Insecticidal Protein (including proteins Cry1Ab and PAT)

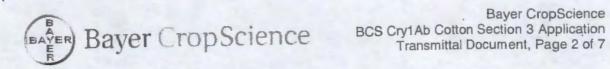
#### DATE

December 22, 2008

#### Author:

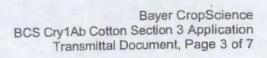
Alejandra (Ali) Scott, Ph.D Regulatory Affairs Manager, Region Americas

Total pages 1 of 7



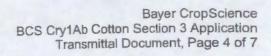
### LIST OF SUBMITTED DOCUMENTS

Volume II Ferullo, J-M. 2008.  Product Characterization of Cry1Ab cotton event T304-40 Unpublished. Bayer CropScience.  MRID Number 47634801  Volume III Nennstiel, D. 2008. Product Characterization – Nutritional Characterization of Cry1Ab cotton event T304-40. Unpublished. Bayer CropScience.  MRID Number 47634802  Volume IV Currier, T. and Massengill, J. 2007. Protein Expression Analysis of Cotton Event T304-40, Expressing Cry1Ab and PAT/bar Proteins, USA, 2007. Unpublished. Bayer CropScience.  MRID Number 47634803	Volume I	Scott, A. 2008. Administrative Documents  Cover letter  Transmittal document  Application for Pesticide Registration (EPA Form 8570-1)  Certification with Respect to Citation of Data (EPA Form 8570-34)  Confidential Statement of Formula (EPA Form 8570-4)  Proposed label  Confidentiality classification  Data matrix  Data matrix blacked out
Product Characterization of Cry1 Ab cotton event T304-40 Unpublished. Bayer CropScience.  MRID Number		MRID Number
Volume III  Nennstiel, D. 2008.  Product Characterization – Nutritional Characterization of Cry1 Ab cotton event T304-40.  Unpublished. Bayer CropScience.  MRID Number	Volume II	Product Characterization of Cry1 Ab cotton event T304-40
Product Characterization – Nutritional Characterization of Cry1Ab cotton event T304-40. Unpublished. Bayer CropScience.  MRID Number		MRID Number 47634801
Volume IV  Currier, T. and Massengill, J. 2007.  Protein Expression Analysis of Cotton Event T304-40, Expressing Cry1 Ab and PAT/bar Proteins, USA, 2007.  Unpublished. Bayer CropScience.	Volume III	Product Characterization – Nutritional Characterization of Cry1Ab cotton event T304-40.
Protein Expression Analysis of Cotton Event T304-40, Expressing Cry1 Ab and PAT/bar Proteins, USA, 2007. Unpublished. Bayer CropScience.		MRID Number47634802
MRID Number47634803	` Volume IV	Protein Expression Analysis of Cotton Event T304-40, Expressing Cry1 Ab and PAT/bar Proteins, USA, 2007.
		MRID Number47634803



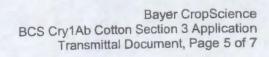


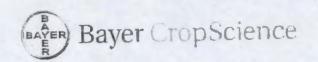
\	Volume V	Martone, A. 2008.  Analyses of Raw Agricultural Commodity (Fuzzy Seed) of Cry1Ab Cotton  Event T304-40 for PAT/bar and Cry1Ab and its Non-transgenic Counterpart for PAT/bar and Cry1Ab Proteins.  Unpublished. Bayer CropScience.
		MRID Number47634804
1	Volume VI	Martone, A. 2008.  Structural and Functional Equivalence of Cry1Ab and PAT/bar Proteins  Produced in Escherichia coli to Cry1Ab and PAT/bar Proteins from Event T304-40 and TwinLink Cotton, Gossypium hirsutum. USA, 2008.  Unpublished. Bayer CropScience.
		47634805
		MRID Number 47634805
	Volume VII	Nennstiel, D. 2008.  ORF Analysis - Toxicology (human health assessment)  Unpublished. Bayer CropScience.
		MRID Number
-	Volume VIII	Rouquié, D. 2007.  Cry1Ab protein: In vitro digestibility study in simulated intestinal fluid.  Unpublished. Bayer CropScience.
		MRID Number
,	Volume IX	Rouquié, D. 2007.  Cry1Ab protein: In vitro digestibility study in human simulated gastric fluid.  Unpublished. Bayer CropScience.
		MRID Number47651102



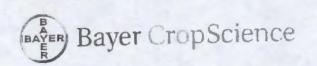


	Volume X	Rouquié, D. 2007. Cry1Ab protein: Epitope homology, N-glycosylation and overall amino acid sequence homology search with known toxins and allergens. Supplement to MRID 46708802 and MRID 46708803
		Unpublished. Bayer CropScience.
		MRID Number47634809
,	Volume XI	Rouquié, D. 2007.  Cry1Ab protein: Acute toxicity by oral gavage in mice.  Unpublished. Bayer CropScience.
		MRID Number
.1	Volume XII	Rouquié, D. 2007.  Cry1Ab Protein: Heat Stability study.  Unpublished. Bayer CropScience.
		MRID Number
,	Volume XIII	Nennstiel, D. 2008.  Toxicology (Human Health Assessment): History of Safe Use History of Safe Use.  Use.  Unpublished. Bayer CropScience.
		MRID Number
1	Volume XIV	Chalmers, A. 2008.  Summary of Non-Target Organism Testing and Assessment of Risk of Gossypium hirsutum Transformation event T304-40 Expressing Cry1Ab Protein.  Unpublished. Bayer CropScience.
		MRID Number47634813



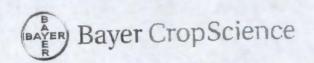


Volume XV	Richards, K. 2008.  Evaluation of the Dietary Effect(s) of a Cry1Ab Protein on Honey Bee Larvae (Apis mellifera L.).  Unpublished. Bayer CropScience.
	MRID Number47651105
Volume XVI	Patnaude, M. 2008.  Laboratory Study to Determine the Effects of Cry1Ab Protein on the Predatory Beetle Coleomegilla maculate.  Unpublished. Bayer CropScience.
	Robinson, T.; Currier, T.; Chalmers, A.  Analysis of Insect Diet tested in Study EB99L008 'Laboratory Study to Determine the Effect of Cry 1Ab protein on the Predatory Beetle,  Coleomegilla maculata' Unpublished Bayer CropScience
	MRID Number
∨olume XVII	Patnaude, M. 2008.  Cry1Ab Protein. Toxicity to Green Lacewing (Chrysoperla rufilabris).  Unpublished. Bayer CropScience.
	MRID Number
Volume XVIII	Patnaude, M. 2008.  Chronic Toxicity to Collembola (Folsomia candida) using Cry1Ab Proteins.  Unpublished. Bayer CropScience.
	MRID Number47651108
Volume XIX	Bushey, D. 2008.  Request for Waivers from the Requirement to Conduct A Non-target Soil Invertebrate Study: Earthworm.  Unpublished. Bayer CropScience.
	MRID Number 47634818



Bayer CropScience BCS Cry1Ab Cotton Section 3 Application Transmittal Document, Page 6 of 7

Volume XX	Sayers, L. 2008.  Cry1Ab Protein – Ten Day Toxicity Test to Water Fleas (Daphnia magna)  Under Static-Renewal Conditions.
	Unpublished. Bayer CropScience.
	MRID Number
Volume XXI	Martone, A. 2008.  The Use of an Insect Heliothis virescens Bioassay to Determine the DT <sub>50</sub> of the Cry1Ab Protein Produced from Escherichia coli after Aerobic Soil Degradation, USA, 2007.  Unpublished. Bayer CropScience.
	MRID Number47634820
Volume XXII	Jesudason, P. 2008  Cry 1Ab: Efficacy Assessment (Field and Laboratory)  Unpublished Bayer CropScience
	MRID Number47634821
Volume XXIII	Bushey, D. 2008  Request for Waiver from the Requirement to Prepare a Public Interest Document. Unpublished. Bayer CropScience
	MRID Number
√ Volume XXIV	Bushey, D. 2008 Request for a Waiver from the Requirement to Develop an Insect Resistance Management Plan. Unpublished. Bayer CropScience.
	MRID Number
Volume XXV	Nennstiel, D, 2008.  Detection Methods – rt PCR.  Unpublished. Bayer CropScience.
	MRID Number47634824



BCS Cry1Ab Cotton Section 3 Application Transmittal Document, Page 7 of 7

Volume XXVI	Nennstiel, D, 2008.  Detection Methods – LFS.  Unpublished. Bayer CropScience.	
	MRID Number47634825	-
➤ Volume XXVII	Nennstiel, D, 2008.  Detection Methods – ELISA.  Unpublished. Bayer CropScience.	
	MRID Number 47634826	



### UNI. \_ STATES ENVIRONMENTAL PROTEC . . 4 AGENCY WASHINGTON, D.C. 20460

January 13, 2009

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

OPP Decision Number: D-404794

EPA File Symbol or Registration Number: 264-RNOU Product Name: BCS CRY1AB COTTON EVENT T304-40

EPA Receipt Date: 30-Dec-2008 EPA Company Number: 264

Company Name: BAYER CROPSCIENCE LP

Ali Scott
BAYER CROPSCIENCE LP
2 T.W. ALEXANDER DRIVE
RESEARCH TRIANGLE PARK, NC 27709

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: B800

NEW AI;EUP;PIP;NON-FOOD/FEED OR CROP DESTRUCT;SAP REQUIRED (SUBMITTED BEFORE NEW AI PACKAGE. \$75K CREDIT TOWARD NEW AI REGISTRATION);

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-8260.

Sincerely,

Front End Processing Staff
Information Technology & Resources Management Division

\*Commercial/financial information may be entitled to confidential treatment\*

BNY MELLON, N.A. PITTEBURGH PA 15262



HE BACK VERIFY FOR AUTHENTICITY

CHECK NO 3100028517

433

PAY:

\*\*\*TWO HUNDRED TWENTY THOUSAND FIVE HUNDRED AND 00/100 DOLLARS\*\*\*

TO THE ORDER ENVIRONMENTAL PROTECTION AGENCY USEPA WASHINGTON FINANCE CENTER PESTICIDE REGISTRATION SERVICE PO BOX 979074

Authorizant Signatures
Chary & Joseph

Can 5. But

ST. LOUIS MO 63197-9000.

#3100028517# #043301601#





UlP/110 BEGBV

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SEPA	Environmen	United States stal Protection and States and Protection and States			No. 2070-0080 legistration Amendment Other	OPP Identifier Numb
		Application	for Pesticide	- Section I		
1. Company/Product No. 264- RIVOU	imber		2. EPA Prod Denise Gro	luot Meneger eenway		oposed Classification
4. Company/Product (N BCS Cry1Ab cotton of	eme) event T304-40		PM#	12	×	Nane Restri
5. Name and Address of Bayer CropScience - 2 T.W. Alexander Dr Research Triangle P	- BioScience	Code)	(b)(i), my p to: EPA Reg	roduct is simila	r or identical in co	FIFRA Section 3(c) imposition and labeli
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Amendment - E: Resubmission in Notification - Ex	response to Agency le	tter dated	🗀 🌣	el printed labels i ency letter dated le Teo* Applications her - Explain belo	on.	

			Section - III			
1. Material This Product Wi	l Be Packaged In:					
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3. Location of Net Contents	Container	/a			ol	ons
		Lithog Paper Stenci	Section - IV			
Name Ali Scott	Rams ovectly bulow for	<i>Joanuncauo</i>	Title Manager, Reg Affairs	T necessary, to p	T	ne No. (Include Area Code
	ny knowingly false or mis		tion all attachments thereto are true ement may be punishable by fin			6. Date Application Received (Stamped)
2. Signature	Ausura		3. Title Manager, Reg Affairs			
4. Typed Name All Scott			5. Data  December 22, 2008			

Cotton seed





## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 1200 Pennsylvania Avenue, N.W. WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of informat and 0.25 hours per response for reregistration and special review activities, including time for comments regarding burden estimate or any other aspect of this collection of information, including time for comments Protection Agency, 1200 Pennsylvania Aveto this address.	reading the instructional luding suggestions for	ns and completing the necessary forms. Send reducing the burden to: Director, Collection
Certification with Respect to	Citation of Data	
Applicant's/Registrant's Name, Address, and Telephone Number Bayer CropScience - BioScience. 2 TW Alexander Dr. RTP, NC 27709 (919) 549	2159	EPA Registration Number/File Symbol 284-
Active Ingredient(s) and/or representative test compound(s) Cry1Ab protein and the genetic material necessary for its production in cotton even	nt T304-40	Date December 22, 2008
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 156 n/s	3)	Product Name BCS Cry1Ab cotton
NOTE: If your product is a 100% repackaging of another purchased EPA-register submit this form. You must submit the Formulator's Exemption Statement (EPA Formulator)		for all the same uses on your label, you do not need to
I am responding to a Data-Call-In Notice, and have included with this form a be used for this purpose).	list of companies s	ent offers of compensation (the Data Matrix form should
SECTION I: METHOD OF DATA SUPI	PORT (Check one i	nethod only)
I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	under th	ng the selective method of support (or cite-all option e selective method), and have included with this form a ad list of data requirements (the Data Matrix form must be
SECTION II: GENERAL	OFFER TO PAY	
I hereby offer and agree to pay compensation, to other persons, with regard to		s application, to the extent required by FIFRA.
I certify that this application for registration, this form for reregistration, or the pata-Call-In response. It indicated in Section I, this application is supported by all data in the Agency's files the substantially similar product, or one or more of the ingredients in this product; and (2) requirements in effect on the date of approval of this application if the application sources.  I certify that for each exclusive use study cited in support of this registration the written permission of the original data submitter to cite that study.  I certify that for each study cited in support of this registration or reregistrate submitter; (b) I have obtained the permission of the original data submitter to use the compensation have expired for the study; (d) the study is in the public literature; or (e) offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(1)(F) and/or 3(c)(1)(F) and/or 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will evidence to the Agency upon request, I understand that the Agency may initiate action FIFRA.	n addition, if the cite at (1) concern the pr is a type of data the ght the initial registr a or reregistration, the ion that is not an ex- study in support of thave notified in w (c)(2)(B) of FIFRA; where ion is to the pies of all offers to the be submitted to the	all option or cite-all option under the selective method is operties or effects of this product or an identical or at would be required to be submitted under the data ation of a product of identical or similar composition and not I am the original data submitter or that I have obtained clusive use study, either: (a) I am the original data this application; (c) all periods of eligibility for riting the company that submitted the study and have and (ii) to commence negotiations to determine the say compensation and evidence of their delivery in Agency upon request. Should I fail to produce such
i certify that the statements I have made on this form and all attache knowingly false or misleading statement may be punishable by fine or impriso		
Signature Au Survi	Date Dec 22, 2008	Typed or Printed Name and Title All Scott, Manager

EPA Form 8570-34 (12-2003) Electronic and Paper versions available. Submit only Paper version.

\*Pages 16-22 - \*Claimed confidential by submitter\*



#### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W. WASHINGTON, D.C. 20460

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# DATA MATRIX Date: December 22 2008 EPA Reg. No.: 264Applicant's/Registrant's Name & Bayer CropScience - BioScience Address 2 T.W. Alexander Drive Research Triangle Park, NC 27709 Ingredient: BCS Cry1Ab protein as expressed in cotton and the genetic material necessary for its production.

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			264	OWN	
			264	OWN	
			264	OWN	
			264	OWN	
			264	OWN	

Signature: Ali Suns

Name and Title: Ali Scott, Regulatory Affairs Manager

Date: December 22, 2008

EPA Form 8570-35 (9-97) Electronic Paper versions available. Submit only Paper version.



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#### DATA MATRIX

Date: December 22 2008

EPA Reg. No.: 264-

Page 2 of 7

Applicant's/Registrant's Name &

Bayer CropScience - BioScience 2 T.W. Alexander Drive Product: BCS Cry1Ab cotton.

Address

Research Triangle Park, NC 27709

Ingredient: BCS Cry1Ab protein as expressed in cotton and the genetic material necessary for its production.

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			264	OWN	
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			264	OWN	
			264	OWN	
			264	OWN	

Signature: Au Suns

Name and Title: Ali Scott, Regulatory Affairs Manager

Date: December 22, 2008

EPA Form 8570-35 (9-97) Electronic Paper versions available. Submit only Paper version.



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#### DATA MATRIX

Date: December 22 2008

EPA Reg. No.: 264-

Page 3 of 7

Applicant's/Registrant's Name &

Bayer CropScience - BioScience 2 T.W. Alexander Drive Product: BCS Cry1Ab cotton.

Address

Research Triangle Park, NC 27709

Ingredient: BCS Cry1Ab protein as expressed in cotton and the genetic material necessary for its production.

264 OWN	Note	Status	Submitter	MRID Number	Guideline Study Name	Guideline Reference Number
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Signature: Au Suns

Name and Title: Ali Scott, Regulatory Affairs Manager

Date: December 22, 2008

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#### DATA MATRIX

Date: December 22 2008

EPA Reg. No.: 264-

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Applicant's/Registrant's Name &

Bayer CropScience - BioScience

Product: BCS Cry1Ab cotton.

Address 2 T.W. Alexander Drive
Research Triangle Park, NC 27709

Ingredient: BCS Cry1Ab protein as expressed in cotton and the genetic material necessary for its production.

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
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Signature: Ali Suns

Name and Title: Ali Scott, Regulatory Affairs Manager

Date: December 22, 2008

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#### DATA MATRIX

Date: December 22 2008

EPA Reg. No.: 264-

Page 5 of 7

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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note

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264	OWN

Signature: Name and Title: Ali Scott, Regulatory Affairs Manager

Date: December 22, 2008

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December 22, 2008

Biopesticides and Pollution Prevention Division (7511C)
Office of Pesticide Programs
U.S. Environmental Protection Agency
One Potomac Yard,
2777 S. Crystal Dr.,
Alexandria, VA 22202

Subject: Registration application for BCS Cry1Ab cotton event T304-40 cotton. Active ingredient *Bacillus thuringiensis* Cry1Ab protein and the genetic material necessary for its production. Confidentiality classifications for Registration application.

The present letter identifies the confidentiality classification for all of the documents supporting this application.

Volume number	Content	Confidentialis classification	
ı	Scott, A. 2008. Administrative Documents.  Cover Letter Transmittal Document Registration Application Form Confidential Statement of Formula (CSF) Proposed Label Confidentiality Classification Data Matrix Data Matrix blacked out	<ul> <li>n/a</li> <li>n/a</li> <li>A</li> <li>C</li> <li>A</li> <li>n/a</li> <li>C</li> <li>A</li> </ul>	
II	Ferullo, J-M. 2008. Product Characterization of Cry1Ab cotton event T304-40.	В	
HI	Nennstiel, D. 2008. Product Characterization – Nutritional Characterization of Cry1Ab cotton event T304-40.	В	
IV	Currier, T. and Massengill, J. 2007. Protein Expression Analysis of Cotton Event T304-40, Expressing Cry1Ab and PAT/bar Proteins, USA, 2007.	В	
٧	Martone, A. 2008. Analyses of Raw Agricultural Commodity (Fuzzy Seed) of Cry1Ab Cotton Event T304-40 for PAT/bar and Cry1Ab and its Non-transgenic Counterpart for PAT/bar and Cry1Ab Proteins.	В	
VI	Martone, A. 2008. Structural and Functional Equivalence of Cry1Ab and PAT/bar Proteins Produced in Escherichia coli to Cry1Ab and PAT/bar Proteins from Event T304-40 and TwinLink Cotton, Gossypium hirsutum. USA, 2008.	В	

VII	Nennstiel, D. 2008. ORF Analysis - Toxicology (human health assessment).	В
VIII	Rouquié, D. 2007. Cry1Ab protein: <i>In vitro</i> digestibility study in simulated intestinal fluid.	В
IX	Rouquié, D. 2007. Cry1Ab protein: <i>In vitro</i> digestibility study in human simulated gastric fluid.	В
X	Rouquié, D. 2007. Cry1Ab protein: Epitope homology, N-glycosylation and overall amino acid sequence homology search with known toxins and allergens. Supplement to MRID 46708802 and MRID 46708803.	В
XI	Rouquié, D. 2007. Cry1Ab protein: Acute toxicity by oral gavage in mice.	В
XII	Rouquié, D. 2007. Cry1Ab Protein: Heat Stability study. Vol XII	В
XIII	Nennstiel, D. 2008. Toxicology (Human Health Assessment): History of Safe Use History of Safe Use.	В
XVI	Chalmers, A. 2008. Summary of Non-Target Organism Testing and Assessment of Risk of <i>Gossypium hirsutum</i> Transformation event T304-40 Expressing Cry1Ab Protein.	В
XV	Richards, K. 2008. Evaluation of the Dietary Effect(s) of a Cry1Ab Protein on Honey Bee Larvae (Apis mellifera L.).	В
XVI	Patnaude, M. 2008. Laboratory Study to Determine the Effects of Cry1Ab Protein on the Predatory Beetle Coleomegilla maculate.	В
XVI	Robinson, T.; Currier, T.; Chalmers, A. Analysis of Insect Diet tested in Study EB99L008 'Laboratory Study to Determine the Effect of Cry 1Ab protein on the Predatory Beetle, <i>Coleomegilla maculata</i> '.	В
XVII	Patnaude, M. 2008. Cry1Ab Protein. Toxicity to Green Lacewing (Chrysoperla rufilabris).	В
XVIII	Patnaude, M. 2008. Chronic Toxicity to Collembola (Folsomia candida) using Cry1Ab Proteins.	В
XVI	Bushey, D. 2008. Request for Waivers from the Requirement to Conduct A Non-target Soil Invertebrate Study: Earthworm. Vol XIX	В
XX	Sayers, L. 2008. Cry1Ab Protein – Ten Day Toxicity Test to Water Fleas ( <i>Daphnia magna</i> ) Under Static-Renewal Conditions.	В
XXI	Martone, A. 2008. The Use of an Insect <i>Heliothis virescens</i> Bioassay to Determine the DT <sub>50</sub> of the Cry1Ab Protein Produced from Escherichia coli after Aerobic Soil Degradation, USA, 2007.	В
XXII	Jesudason, P. 2008. Cry 1Ab: Efficacy Assessment (Field and Laboratory).	В
XXIII	Bushey, D. 2008. Request for Waiver from the Requirement to Prepare a Public Interest Document.	В
XXIV	Bushey, D. 2008. Request for a Waiver from the Requirement to Develop an Insect Resistance Management Plan.	В
XXV	Nennstiel, D, 2008. Detection Methods – rt PCR. Vol XXV	В
XXVI	Nennstiel, D, 2008. Detection Methods – LFS. Vol XXVI	В
XXVII	Nennstiel, D, 2008. Detection Methods – ELISA. Vol XXVII	В

